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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,915	07/22/2003	D. Russell Pflueger	QMI-3077	7109

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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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12/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,915

Applicant(s)

PFLUEGER ET AL.

Examiner

Nihir Patel

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10.01.2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-54, 66-68, 70-78 and 80-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-54, 66-68, 70-78, 80-83, 85-94 and 96-107 is/are rejected.
- 7) ☒ Claim(s) 55, 84, and 95 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10.01.2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 52-55, 66-68, 70-78, 80-107 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

2. Claim **55** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. **Claim 55 depends from 50 which is canceled and therefore cannot be examined.**

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **82, 83, 85-94, 97 and 99-107** are rejected under 35 U.S.C. 102(e) as being anticipated by Conrad et al. (US 6,250,307).
5. **As to claim 82**, Conrad teaches an appliance that comprises two elongated curved elements of a bio-compatible material (**see figures 20-23; column 7 lines 10-15**), each of the curved elements having a substantially circular dimension between a first end and a second end

extending through more than 90 degrees of a circle (**see figures 20-23**), the two elements being coupled together at respective first and second ends, and being spaced apart from each other between the first and second ends to define an open interior space therebetween (**see figures 20-23**), the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and, when so placed, being effective in treating sleep apnea (**see figures 20-23; column 6 lines 60-67**).

6. As to **claim 83**, Conrad teaches an apparatus wherein the substantially circular dimension between the first and the second end extends through at least 180 degrees of a circle (**see figures 20-23**).

7. As to **claim 85**, Conrad teaches an apparatus wherein each of the elongated elements comprises a resilient wire (**see figures 20-23 and column 7 lines 10-15**).

8. As to **claim 86**, Conrad teaches an apparatus wherein the appliance comprises a C-shpaed structure (**see figure 11**).

9. As to **claim 87**, Conrad teaches an apparatus wherein the two elongated elements are portions of the same structure (**see figures 20-23**).

10. As to **claim 88**, Conrad teaches an apparatus wherein the appliance has a lateral dimension defined by the distance between the first and second ends and a maximum longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension (**see figures 20-23**).

11. As to **claim 89**, Conrad teaches an apparatus wherein the appliance has a concave loop configuration when the appliance is so placed in the oropharyngeal region (**see figure 23**).
12. As to **claim 90**, Conrad teaches an apparatus wherein the appliance is sized and structured to be place below a soft palate of a human or animal (**see column 7 lines 1-10**).
13. As to **claim 91**, Conrad teaches an apparatus wherein the appliance is made of an elastic spring memory material (**see column 7 lines 10-15**).
14. As to **claim 92**, Conrad teaches an apparatus wherein the appliance is made of nitinol (**see column 7 lines 10-15**).
15. As to **claim 93**, Conrad teaches an appliance that comprises an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions (**see figures 20-23**), The appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C shaped deployed configuration (**see figure 11**) in which at least one of the elongated elements extends generally laterally across the posterior wall and the first and second portions bear against and provide an opening force against the lateral walls of the oropharyngeal region (**see figures 11 and 20-23**).
16. As to **claim 94**, Conrad teaches an apparatus wherein the appliance defines an open interior space between the spaced apart elongated elements (**see figures 20-23**).
17. As to **claim 97**, Conrad teaches an apparatus wherein, in the substantially C-shaped configuration, the first and second end portions define a gap therebetween (**see figures 11 and 20-23**).

18. As to **claims 99, 101 and 107**, Conrad teaches an apparatus wherein the appliance comprises biocompatible material (see **column 5 lines 65-67; column 6 lines 1-10; and column 7 lines 10-15**).

19. As to **claims 100 and 102**, Conrad teaches an appliance that comprises a single continuous loop comprising first and second rounded end portions and two spaced apart elongated elements extending between the first and second end portions such that the loop defines an open interior space between the spaced apart elongated elements (see **figures 20-23**), the appliance being sized for introduction into an oropharyngeal region of a human or animal (see **column 6 lines 60-67**) and deploying in a C shaped deployed configuration in which the elongated elements extending generally laterally across the posterior wall and the first and second end portions bearing against and providing an opening force against the lateral walls of the oropharyngeal region (see **column 6 lines 60-67 and column 7 lines 1-10**).

20. As to **claim 103**, Conrad teaches an apparatus wherein the appliance comprises a substantially C-shaped configuration with the first and second end portions defining a gap therebetween when released within the oropharyngeal region (see **figure 11**).

21. As to **claim 104**, Conrad teaches an apparatus wherein the appliance comprises placing the appliance at least partially in or beneath the mucosal layer of the oropharyngeal region (see **column 6 lines 60-67**).

22. As to **claim 105**, Conrad teaches an apparatus wherein the appliance comprises providing the appliance in a deformed first configuration, and wherein releasing the appliance within the oropharyngeal region allows the appliance to reconfigure to a deployed second configuration within the oropharyngeal region (see **figures 20-23**).

23. As to **claim 106**, Conrad teaches an apparatus wherein the deployed second configuration comprises a C-shaped configuration (**see figure 11**).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. Claims **52-54, 66-68, 70-78, 81 and 98** are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US 6,250,307).

27. As to **claims 52-54, 66-68, 70-78 and 81**, Conrad substantially discloses a method step of providing an appliance made of a biocompatible metal (**see column 7 lines 10-15**) below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal (**see column 6 lines 60-67**), the appliance so provided having at least two laterally positioned elements substantially, longitudinally spaced

apart from each other to define an open interior space therebetween and providing an opening force against the lateral walls of the oropharyngeal region (**see figures 20-23**).

The method steps would have been obvious because they would have resulted from the use of the device of Conrad.

28. **As to claim 98**, Conrad substantially discloses the claimed invention; see rejection of claim 93 above, Conrad substantially discloses the appliance expanding in the C configuration (see figure 11) but does not provide a numerical value of how much in diameters (32mm or greater) the appliance expands. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Conrad's invention by providing an appliance that expands 32 mm or greater in diameter in order to reduce or prevent snoring, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

29. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US 6,250,307) in view of Conrad et al. (US 6,453,905).

30. **As to claim 96**, Conrad '307 substantially discloses the claimed invention; see rejection of claim 93 above, but does not disclose an elongate loop that comprises a substantially mesh structure. Conrad '905 discloses an apparatus that does provide an elongate loop that comprises a substantially mesh structure (**see claim 7**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Conrad's ('307) invention by providing an elongate loop that comprises a substantially mesh structure as taught by Conrad '905 in order to reduce or prevent snoring.

Allowable Subject Matter

31. Claims **84 and 95** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach an appliance that only two elongated curved elements, each of the curved elements has a curved length extending from the first end to the second end, and the first end and the second end define a gap therebetween, extending outwardly away from the first and second curved elements having a gap length which is reduced relative to the curved length of each of the curved elements.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772


Nihir Patel


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12/10/07